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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,340	08/06/2001	Stephane Bejanin	91.US2.REG	6695
23557	7590	11/30/2004	EXAMINER	
SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			LY, CHEYNE D	
		ART UNIT	PAPER NUMBER	
			1631	

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/924,340	BEJANIN ET AL.	
	Examiner Cheyne D Ly	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 15 October 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 34-49 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 34-49 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/11/02.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
 5) Notice of Informal Patent Application (PTO-152)
 6) Other: Result 1 (Sequence Alignment).

DETAILED ACTION

1. Applicant's election without traversal of Group III, claims 21-24, filed October 15, 2003, is acknowledged.
2. The cancellation of claims 1-33 and addition of claims 34-49 have been acknowledged.
3. Claims 34-49 are examined on the merits.

OBJECTIONS

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (Page 341, Lines 14-15). Applicant(s) is/are required to delete the embedded hyperlink and/or other form of browser-executable code, or deactivate the hyperlink. See MPEP § 608.01.
5. The title of the invention is not descriptive because the instant title is directed to human cDNAs and proteins while the elected subject matter is directed to an isolated polypeptide. A new title is required that is clearly indicative of the invention to which the claims are directed.

CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
7. Claims 37, 40, 43, 46, and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
8. Claim 37 recites the limitation of "at least six consecutive amino acids and spans positions 97 through 98" causes said claim to be vague and indefinite because it is not clear how "six consecutive amino acids" would fit into "positions 97 through 98." Clarification of the

metes and bounds is require. Claims 40, 43, 46, and 49 are rejected for being dependent from claim 37.

LACK OF UTILITY UNDER 35 U.S.C. § 101

9. The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

10. The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

11. Claims 34-49 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

12. The critical limitation of claims 34-49 is the polypeptide of the sequence describe in SEQ ID NO: 58. Applicant discloses that cDNA of SEQ ID NO. 57, which encodes the polypeptide of SEQ ID NO. 58, is a novel splice variant of the human alpha 1 type XVI collagen gene (GB M92642.1). From the sequence similarities between the sequence SEQ ID NO. 57 and the sequence of accession number M92642, Applicant concludes that the claimed polypeptide is a variant of the human alpha 1 type XVI collagen gene. Applicant asserts that said conclusion supports the asserted patentable utility of the claimed polypeptide as directed to collagen related diseases (pages 214-218).

13. For example, the specification states that the polypeptide sequences may be useful for an *in vitro* assay to various proteases which degrade or denature collagen, in animal models, diagnose diseases or disorders associated with abnormalities of the metabolism of collagen or the monitoring of collagen degradation etc. (pages 214-218). The above-mentioned list of desirable utility for the claimed sequence falls short of a readily available utility. These are non-specific uses that are applicable to a large family of structurally related collagen related proteins, however, not particular or specific to the polypeptide being claimed.

14. It is noted that Pan et al. describes the isolation of the cDNA sequence with the accession number of GB M92642.1, and attributes said sequence as the human alpha 1 type XVI collagen gene by chromosomal location analysis and sequence alignment (Pan et al., Abstract etc. and page 6567-6568, Results §). Pan et al. concludes that the “structural similarities between the

$\alpha 1$ (XVI) collagen and the FACIT group raise the intriguing possibility that the $\alpha 1$ (XVI) collagen may serve similar functions" (Pan et al., page 6569, column 1, last paragraph). Pan et al. does not provide any data beyond the isolation and sequence alignment that would specifically support that the human alpha 1 type XVI collagen gene is responsible for any collagen related diseases as asserted by Applicant. Applicant's disclosure of sequence similarities between the sequence SEQ ID NO. 57 and the sequence of GB M92642.1 only supports that the claimed polypeptide has an "intriguing possibility" of having similar functions as the FACIT proteins. Therefore, the specification does not provide any specific support for the asserted patentable utility of the claimed polypeptide as directed to collagen related diseases.

15. Further, the claimed polypeptide is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. It is noted that the instant specification discloses the isolation and studying of the claimed polypeptide. However, the identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved, such as the polypeptide sequence of SEQ ID NO: 58, does not define a "real world" context for use. Similarly, the other listed utilities and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to many such compounds in the large family of structurally related of collagen proteins.

CLAIMS REJECTED UNDER U.S.C. § 112, FIRST PARAGRAPH

16. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly

connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

LACK OF ENABLEMENT

17. Claims 34-49 are rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed sequence.

18. The claimed invention is not supported by a specific, substantial, and credible utility or a well-established utility for the reasons set forth above (refer to 35 U.S.C. § 101 rejection), one skilled in the art would not know how to use the claimed invention.

LACK OF WRITTEN DESCRIPTION

19. Claims 41-46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

20. The specification discloses the polypeptide sequence corresponding to SEQ ID NO: 58. Claims 41-46 are directed allelic variants and "polypeptide having at least 90%..., 99%". None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does

not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

21. With the exception of SEQ ID NO: 58, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that: ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc. , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood , 107 F.3d at 1572, 41 USPQ2d at 1966.

22. Therefore, only SEQ ID NO: 58, but not the full breadth of the claims 41-46 meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

CLAIM REJECTIONS - 35 USC § 102

23. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

24. Claims 37, 40-43, 46, and 49 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Pan et al. (1992).

25. Pan et al. discloses a cDNA sequence with the accession number of GB M92642 encoding the human alpha 1 type XVI collagen polypeptide (Pan et al., page 6565, column 2, Footnote §, and Figure 2) which is inherently an allelic variant of the claimed polypeptide as supported by the instant specification (page 214, lines 1-8), as in instant claims 41-43.

26. Due to the vague and indefinite of claims 37, 40, and 46 as discussed above, the limitation of “at least six consecutive amino acids and spans positions 97 through 98” has been interpreted reasonably broad. Pan et al. disclose GB M92642 comprising a fragment (amino acids GP) that “spans positions 97 through 98 of SEQ ID NO: 58” (Result 1, page 3), as in claims 37, 40, and 46.

27. Pan et al. discloses that the collagenous polypeptide beginning with a hydrophobic signal peptide, suggesting that the predicted protein is secreted into intracellular space (page 6568, column 2, Discussion §, lines 1-4). It is noted that the phrase “physiologically acceptable carrier” has been disclosed as being used interchangeably with other phrases (page 18) does not specifically defined the phrase “physiologically acceptable carrier”. Therefore, the signal peptide of Pan et al. has been reasonably interpreted as a “physiologically acceptable carrier”, as in instant claim 49.

28. The Pan et al. reference has not been provided with this Office Action because Applicant provided said reference on April 11, 2002.

CONCLUSION

29. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

30. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

31. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

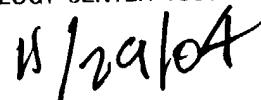
Art Unit: 1631

32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

33. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

C. Dune Ly
11/24/04


MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600



RESULT 1

S23810

collagen alpha 1 (XVI) chain precursor - human

N; Alternate names: procollagen alpha 1 (XVI) chain

C; Species: Homo sapiens (man)

C; Date: 28-Oct-1994 #sequence_revision 28-Oct-1994 #text_change 15-Sep-2003

C; Accession: S23810; PQ0612; S08012

R; Pan, T.C.; Zhang, R.Z.; Mattei, M.G.; Timpl, R.; Chu, M.L.

Proc. Natl. Acad. Sci. U.S.A. 89, 6565-6569, 1992

A; Title: Cloning and chromosomal location of human alpha₁(XVI) collagen.

A; Reference number: S23810; MUID:92335339; PMID:1631157

A; Accession: S23810

A; Molecule type: mRNA

A; Residues: 1-1603 <PAN>

A; Cross-references: EMBL:M92642; NID:9180757; PIDN:AAA58427.1; PID:9180758

A; Experimental source: skin fibroblasts

R; Yamaguchi, N.; Kimura, S.; McBride, O.W.; Hori, H.; Yamada, Y.; Kanamori, T.; Yamakoshi, H.; Nagai, Y.

J. Biochem. 112, 856-863, 1992

A; Title: Molecular cloning and partial characterization of a novel collagen chain, alpha₁(XVI), consisting of repetitive collagenous domains and cysteine-containing non-collagenous segments.

A; Reference number: PQ0612; MUID:93203161; PMID:1284248

A; Accession: PQ0612

A; Molecule type: mRNA

A; Residues: 'GGR', 421-536, 'P', 538-1159, 'P', 1161-1162, 'P', 1164, 'P', 1166-1603 <YAM>

A; Cross-references: GB:S557132; NID:g298641; PIDN:AAB25797.1; PID:g298642

A; Experimental source: placenta

R; Kimura, S.

Submitted to the EMBL Data Library, April 1989

A; Description: Partial nucleotide and amino acid sequence of a collagen-like protein from human placenta.

A; Reference number: S08012

A; Accession: S08012

A; Molecule type: mRNA

A; Residues: 403-419, 'GR', 421-536, 'P', 538-846, 'VM' <KIM>

A; Cross-references: EMBL:X14963; NID:g29984; PIDN:CDA33085.1; PID:9930048

C; Comment: Prolines and lysines at the third position of the tripeptide repeating unit (G-X-Y) are hydroxylated to varying extents. Prolines are predominately 4-hydroxylated. Lysines are 5-hydroxylated and subsequently O-glycosylated.

C; Genetics:

A; Gene: GDB:COL16A1

A; Cross-references: GDB:134045; OMIM:120326

A;Map position: 1p34-1p34
C;Complex: type XVI collagen may be a homotrimer, or a heterotrimer of two alpha 1(XVI) chains and one alpha 2(XVI) chain

C;Function:

A;Description: structural component of extracellular fibrous polymer as a minor form produced by placental, dermal and lung fibroblasts, and by epidermal keratinocytes
A;Note: may play a role in forming elastic connections at fibril surfaces
C;Keywords: cell binding; coiled coil; extracellular matrix; glycoprotein; hydroxylysine; hydroxyproline; trimer; triple helix
F;1-21/Domain: signal sequence #status predicted <SIG>
F;22-1603/Product: collagen alpha 1 (XVI) chain #status predicted <MAT>
F;22-333/Domain: amino-terminal nonhelical #status predicted <NC11>
F;334-1577/Region: interrupted helical
F;334-360/Domain: collagenous COL10 #status predicted <COL10>
F;375-505/Domain: collagenous COL9 #status predicted <COL9>
F;521-554/Domain: collagenous COL8 #status predicted <COL8>
F;539-541/Region: cell attachment (R-G-D) motif
F;572-630/Domain: collagenous COL7 #status predicted <COL7>
F;652-722/Domain: collagenous COL6 #status predicted <COL6>
F;738-875/Domain: collagenous COL5 #status predicted <COL5>
F;887-938/Domain: collagenous COL4 #status predicted <COL4>
F;973-987/Domain: collagenous COL3 #status predicted <COL3>
F;1005-1007/Region: cell attachment (R-G-D) motif
F;1011-1432/Domain: collagenous COL2 #status predicted <COL2>
F;1226-1228/Region: cell attachment (R-G-D) motif
F;1472-1577/Domain: collagenous COL1 #status predicted <COL1>
F;1578-1603/Domain: carboxyl-terminal nonhelical #status predicted <NC01>
F;47,327/Binding site: carbohydrate (Asn) (covalent) #status predicted

Query Match 88.3%; Score 840.5; DB 2; Length 1603;
Best Local Similarity 44.5%; Pred. No. 1.6e-46;
Matches 163; Conservative 0; Mismatches 0; Indels 203; Gaps 1;

QY	1	MGPPGFKGKGTGHGPLPGPKGDCCGKGPGPPGSTGRPGAEGEPEGAMGPQQGRPGPPGPGHVGPPGP 60
Db	1238	MGPPGFKGKGTGHGPLPGPKGDCCGKGPGPPGSTGRPGAEGEPEGAMGPQQGRPGPPGPGHVGPPGP 1297
QY	61	PGQPGPAGISAVGLKGDRGATGERGLAGLPGQ----- 92
Db	1298	PGQPGPAGISAVGLKGDRGATGERGLAGLPGQPGPPGPPGEPGTDGAAAGKEGPPGKQ 1357

QY	93	--	- - - - -	92
Db	1358	GFYGPPGPKGDPGAAQQKGQAGEKGRAGMPGGPKSGSMGPVGPAGPGERGHPGAPGPS	1417	
QY	93	--	- - - - -	92
Db	1418	GSPGLPVGPGSMGDMVNYDEIKRFTIRQEIIKMFDERMAYYTSRMQFPMEMAAAPGRPGPP	1477	
QY	93	--	- - - - -	PGPPG 97
Db	1478	GKDGAAPGRPGAPGSPGLPQIGREGRQGLPGVRGLPGTTKGEKDIGIAGENGLPGPPG	1537	
QY	98	PQGPPGYGMGATGPMQGQGIPGGIPGPPGPMQPGKAGHCNPSDCFGAMPMEQQYPPMKT	157	
Db	1538	PQGPPGYGMGATGPMQGQGIPGGIPGPPGPMQPGKAGHCNPSDCFGAMPMEQQYPPMKT	1597	
QY	158	MKGPFQ 163		
Db	1598	MKGPFQ 1603		